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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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AZUR PHARMA INC.,

Case No.: 10 cv 207 (NRB)

Plaintiff,

-against-

TRIGEN LABORATORIES, INC.,

**AMENDED COMPLAINT WITH
JURY DEMAND**

Defendant.
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Plaintiff, Azur Pharma, Inc. ("Azur"), by and through its counsel, as and for its
Amended Complaint against Trigen Laboratories ("Trigen"), states as follows:

NATURE OF THIS ACTION

1. This action is brought under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(b), and arises out of Trigen's intentionally false and misleading descriptions and representations of fact concerning, and misrepresentations about, the nature, characteristics and qualities of, its pre-natal products Taron EC Cal ("Taron"), Taron EC Calcium with DHA ("Taron with DHA") and Folivane-EC Calcium DHA ("Folivane," with Taron and Taron with DHA, collectively, the "Trigen Products").

2. Prior to the launch of the Trigen Products, Azur had developed and launched pre-natal vitamins which it markets, has marketed, advertises, has advertised,

sells and has sold under the registered trademark names Gesticare®, Gesticare® with DHA, and Gesticare® with DHA DR (collectively, the “Gesticare® Products”).

3. As set forth below, Trigen markets the Trigen Products as lower cost alternatives to the Gesticare® Products when, in fact, they are not equivalents to those products.

4. Upon information and belief, Trigen, on its product packaging and product inserts, makes false and misleading representations of fact that the Trigen Products contain ingredients, ingredient strengths, and a bi-phasic release mechanism which are the same as those of the Gesticare® Products, so that drug data publishing services (the “Drug Publishing Services”), drug formularies, the prescribing physicians and pharmacists, among others, will believe that the Trigen Products are equivalent to the Gesticare® Products.

5. Upon information and belief, Trigen has made, and continues to make, the false and misleading representations of fact to Drug Publishing Services such as First Databank, Medi-Span, and Red Book, that the Trigen Products contain ingredients, ingredient strengths, and a bi-phasic release mechanism which are the same as those of the Gesticare® Products, because it knows that the drug data publishing services, which identify for the prescribing physicians and pharmacists, among others, equivalent pharmaceutical products, will rely on Trigen’s false representations and be induced to erroneously list the Trigen Products as equivalent to the Gesticare® Products.

6. The clear result of Trigen’s intentionally false statements and misleading conduct is that the Trigen Products appear in the data bases of Drug Publishing Services as lower cost alternatives to the Gesticare® Products. This, in turn, inevitably will result

in numerous formularies listing the Trigen Products as generic or equivalent products to the Gesticare® Products when, in fact, they are not equivalent at all.

7. On information and belief, the manufacture of the Trigen Products is not conducted in accordance with Good Manufacturing Practices (“GMP”) as required under Federal regulations.

8. Unless enjoined by this Court, Trigen’s unlawful conduct will cause Azur to lose not only sales and marketing opportunities, but also the goodwill of patients, physicians, pharmacists, and other participants in the marketplace for prescription drugs.

9. In addition, as set forth below, on information and belief, Trigen’s unlawful conduct poses a potential health risk to patients.

10. For these reasons, Azur brings this action seeking both injunctive relief ,monetary damages.

THE PARTIES

11. Azur is a New York corporation, having its principal place of business at 1818 Market Street, Suite 2350, Philadelphia, Pennsylvania 19103.

12. Upon information and belief, Trigen is a New Jersey corporation, having its principal place of business at 2400 Main Street, Suite 6, Sayreville, New Jersey 08872.

JURISDICTION AND VENUE

13. This Court has original jurisdiction over the subject matter of this lawsuit under 15 U.S.C. §§ 1116 and 1121 and under 28 U.S.C. §§ 1331 and 1338 for claims arising out of Trigen’s violations of Section 43(a) of the Lanham Act.

14. This Court has personal jurisdiction over Trigen because Trigen conducts business in this District.

15. Venue is proper in this District under 28 U.S.C. § 1391(c), because Trigen is subject to personal jurisdiction in this District, and therefore resides in this District.

STATEMENT OF FACTS

16. Azur is a private pharmaceutical company focused on health products related to the central nervous system, women's health, and urological issues.

17. In and around October of 2008, Azur began producing, advertising and selling its Gesticare® Products.

18. Gesticare®, Gesticare® with DHA, and Gesticare® with DHA DR are vitamins and mineral supplements prescribed to pregnant women.

19. The Gesticare® Products were specially formulated to address the issue of competition for uptake of iron and calcium in the gastrointestinal tract. That is, calcium inhibits iron absorption. To enable the consumer to take one tablet that includes both calcium and iron without the calcium inhibiting the body's absorption of the iron, the Gesticare® Products were formulated with proprietary and patent pending bi-phasic technology, which enables an immediate release of iron upon entering the acidic stomach, and a delayed release technology, which results in the subsequent, calcium release. All of the Gesticare® Products utilize this bi-phasic technology.

20. Gesticare® with DHA and Gesticare® with DHA DR were developed to include an Omega 3 fatty acid component - - Docosahexaenoic Acid ("DHA") - - that is believed to be beneficial for infant development. Gesticare® with DHA and Gesticare® with DHA DR utilize a proprietary patented procedure to extract DHA from algae rather than from the more commonly utilized source of fish oil.

21. Since Azur began producing and commercializing the Gesticare® Products over one year ago, it has invested significant money, time and effort to establish those products as leading nutritional supplements for pregnant women.

22. Azur invested in the development of its proprietary technology which establishes a pH dependent release of calcium.

23. Azur also has invested, and continues to invest, in marketing, advertising and branding activities to publicize its Gesticare® Products to the relevant health care professionals to establish the Gesticare® Products as market leaders.

24. Based upon its significant investment in the Gesticare® Products, physicians, among others, have come to recognize Azur's products as the leading bi-phasic nutritional supplements for pregnant women.

25. In 2009, Azur had gross sales of \$7.179 million of its Gesticare® Products.

26. Upon information and belief, Trigen has begun to market its pre-natal vitamins, the Trigen Products, as lower cost alternatives to the Gesticare® Products when, in fact, they are not equivalents.

27. Upon information and belief, the Trigen Products do not utilize a true bi-phasic release mechanism, which distinguishes the Gesticare® Products.

28. Upon information and belief, the ingredients and ingredient strengths of the Trigen Products are not the same as the ingredients and ingredient strengths of the Gesticare® Products.

29. Upon information and belief, (i) Taron consists of a multi-vitamin and multi-mineral tablet; (ii) Taron with DHA consists of (a) a multi-vitamin and multi-

mineral tablet which is the same as the Taron tablet and (b) a red soft gel DHA capsule; and (iii) Folivane consists of (a) a multi-vitamin and multi-mineral tablet and (b) a red soft gel DHA capsule.

30. Upon information and belief, the soft gel DHA capsule component of the Taron with DHA and Folivane products contain significant amounts of Eicosapentaenoic Acid ("EPA"), an Omega-3 fatty acid which produced when DHA is manufactured from fish oil, which has been linked to a risk of bleeding. Because the DHA in Gesticare® with DHA and Gesticare® with DHA DR is derived from algae, not fish oil, EPA is not present in any significant amount in either Gesticare® with DHA or Gesticare® with DHA DR.

31. Upon information and belief, Trigen has made, and continues to make, false and misleading representations of fact on product packaging and product inserts that the Trigen Products contain ingredients, ingredient strengths, and a bi-phasic release mechanism which are the same as those of the Gesticare® Products, so that the Drug Publishing Services, drug formularies, the prescribing physicians and pharmacists, among others, will believe that the Trigen Products are equivalent to the Gesticare® Products.

32. Upon information and belief, Trigen is well aware that physicians, pharmacists and health care organizations, in the process of prescribing or approving payment for prescription drugs, consult the Drug Publishing Services, such as Medi-Span, First Databank, Red Book and Gold Standard. The Drug Publishing Services list drugs as well as their generic equivalents. Often, the lower cost alternative will be the one prescribed or dispensed, or the health care agency will insist on prescriptions of the less expensive alternative.

33. Trigen's intentionally false representations that the Trigen Products are the same as the Gesticare® Products has led the Drug Publishing Services to identify the Trigen Products as lower cost alternatives to the Gesticare® Products, which, in turn inevitably will lead to numerous formularies incorrectly listing the Trigen Products as generic or equivalent products to the Gesticare® Products.

34. Drug Publishing Services, physicians, pharmacists, and other participants in the marketplace for prescription drug products rely upon drug manufacturers to accurately identify the active ingredients in their drug products, and the amounts in which those active ingredients are present.

35. Physicians, pharmacists, and other participants in the marketplace for prescription drug products also rely upon the Drug Publishing Services' generic designators and substitutable products, which now erroneously list the Trigen Products as valid substitutes for the Gesticare® Products.

36. The Drug Publishing Services, physicians, pharmacists, and other participants in the marketplace for prescription drug products have been misled by Trigen's false and misleading statements, and patients' health and safety may be put at risk as a result.

FIRST CLAIM FOR RELIEF
(Violation of the Lanham Act)

37. Azur incorporates paragraphs 1-36 as if fully set forth herein.

38. Trigen advertises, markets, promotes, sells, and distributes the Trigen Products as generic or equivalent to the Gesticare® Products to physicians, pharmacies and patients, including wholesalers, retailers, chains, distributors, mail order houses, and independent pharmacies. These acts constitute false and misleading descriptions of fact

and false and misleading representations of fact in commercial promotion that misrepresent the nature, characteristics and qualities of the Trigen Products in violation of Section 43(a) of the Lanham Act.

39. Azur has demanded that Trigen cease and desist from further making any false or misleading claims that (i) its products are generic, identical to, or a substitute for the Gesticare® Products, or (ii) induce the Drug Publishing Services to list such products as identical to or a substitute for the Gesticare® Products.

40. Trigen has ignored Azur's demands and continues its unlawful actions as described herein. Upon information and belief, the foregoing unlawful acts have been and continue to be deliberate, willful, and wanton.

41. Due to Trigen's false advertising and misleading claims, Azur will suffer actual damages in the form of lost sales and marketing opportunities, in an amount to be determined at trial, and will suffer both monetary damages and other damages, as well as irreparable injury, including the goodwill of consumers, physicians and pharmacists, and loss of market share, for which it has no adequate remedy at law.

WHEREFORE Azur Pharma, Inc. requests that this Court:

- (a) Enter judgment in favor of Azur;
- (b) Grant a preliminary and permanent injunction (1) enjoining Trigen from marketing or selling, or making claims that would cause the Trigen Products to be listed as generic substitutes for the Gesticare® Products, (2) requiring Trigen to notify all of the Drug Publishing Services that the Trigen Products (i) do not contain the same amounts of the same active ingredients or release mechanism as the Gesticare® Products, (ii) are not generics of or equivalent to the Gesticare® Products, and (iii) should not be listed as

alternatives to the Gesticare® Products, and (3) requiring Trigen to recall all Trigen Products from the marketplace, because such products contain false advertisements and are mislabeled and adulterated;

(c) Order Trigen to pay compensatory damages to Azur in an amount to be determined at trial;

(d) Order Trigen to pay treble damages pursuant to 15 U.S.C. § 1117;

(e) Order Trigen to disgorge all profits wrongfully derived from the false and misleading claims complained of herein pursuant to 15 U.S.C. § 1117;

(f) Order Trigen to pay Azur's litigation expenses, including reasonable attorneys' fees and costs of this action, pursuant to 15 U.S.C. § 1117;

(g) Order Trigen to pay prejudgment interest to Azur; and

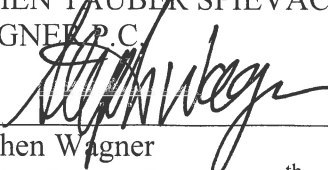
(h) Award Azur such other and further relief as the Court may deem just and proper.

Jury Demand

Azur demands trial by a jury on all jury-triable issues in the Amended Complaint as provided by Rule 38 of the Federal Rules of Civil Procedure.

Dated: New York, New York
March 10, 2010

Respectfully submitted,
COHEN TAUBER SPIEVACK &
WAGNER P.C.

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